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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,746	03/15/2001	Theodore S. Jardetzky	AL-9-C2	5346

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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	7

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/809,746	Applicant(s) JARDETZKY ET AL.	
	Examiner John S Brusca	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

    1. Claims 1-3 drawn to a three dimensional model of a human IgE Fc region, classified in class 702, subclass 19.

    2. Claims 4 and 6, drawn to a human IgE Fc polypeptide, classified in class 530, subclass 387.1.

    3. Claim 5, drawn to a method of using vapor diffusion to make a crystal of a human IgE Fc region, classified in class 530, subclass 418.

    4. Claims 7-9, drawn to polynucleotides encoding a human IgE Fc region, classified in class 536, subclass 23.53.

    5. Claim 11, drawn to a method of making a human IgE Fc polypeptide, classified in class 435, subclass 69.1.

    6. Claim 12, drawn to a method of assay of structures that inhibit binding of human IgE and FceRIa, classified in class 435, subclass 7.1.

    7. Claims 13-15, drawn to an inhibitor of binding of human IgE and FceRIa, therapeutic compositions comprising the inhibitor, and therapeutic methods of use of the inhibitor, classified in class 424, subclass 78.08.

    8. Claims 16 and 17, drawn to a method to improve the function of an antibody, classified in class 435, subclass 440.

9. Claims 18 and 19, drawn to a peptide fragment of an antibody that binds FceRIa, classified in class 530, subclass 387.1.

10. Claim 20, drawn to a polynucleotide encoding a fragment of an antibody that binds FceRIa, classified in class 536, subclass 23.53.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions 1 and inventions 2, 3, 4, 5, 8, 9, and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the three dimensional and methods of making of invention 1 are not used in or produced by the inventions 2, 3, 4, 5, 8, 9, and 10.

Inventions 1 and inventions 6 and 7 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the three dimensional model of invention 1 could be used to study structures that bind to IgE.

Inventions 3 and 2 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein crystals of invention 2 could be made by other crystallization methods known in the art.

Inventions 2 and inventions 4, 5, 6, 7, 8, 9, and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of invention 2 are not used in or produced by the methods of inventions 5, 6, or 8 and are structurally and functionally different than the polynucleotides or polypeptides of inventions 4, 7, 9, and 10.

Inventions 3 and 4, 5, 6, 7, 8, 9, and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of making a crystal of invention 3 comprises different steps and produces different results from the methods of inventions 5, 6, and 8, and does not use or produce the polypeptides or polynucleotides of inventions 4, 7, 9 and 10.

Inventions 4 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of invention 4 could be used as a probe.

Inventions 4 and inventions 6, 7, 8, 9, and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of invention 4 are structurally and functionally different

from the polynucleotides and polypeptides of inventions 7, 9, and 10 and are not used in or produced by the methods of inventions 6, or 8.

Inventions 5 and inventions 6, 7, 8, 9, and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the expression method of invention 5 comprises different steps and produces different results than the methods of inventions 6 and 8, and does not use or produce the polypeptides or polynucleotides of inventions 7, 9, or 10.

Inventions 6 and inventions 7, 8, 9, and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of invention 6 comprises different steps and produces different results from the methods of invention 8 and does not produce or use polypeptides or polynucleotides and therefore does not produce or use the molecules of inventions 7, 9, or 10.

Inventions 7 and inventions 8, 9, and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inhibitors of invention 7 and their methods of therapeutic use are not used or produced by the method of invention 8, and are structurally and functionally different from the polypeptides and polynucleotides of inventions 9 and 10.

Inventions 8 and inventions 9 and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of invention 8 does not use or produce the polypeptides or polynucleotides of inventions 9 and 10.

Inventions 9 and 10 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to functionally and structurally different molecules.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group 2 is not required for Group 9, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group 4 is not required for Group 10, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

For each of inventions 1, 6, 7, and 8 the species are the atomic coordinates of tables 1, 2, and 3.

For invention 9 the species are the different fragments listed in the Markush group of claim 18 and additionally the species listed in the Markush group of claim 19.

For invention 10 the species are the different fragments listed in the Markush group of claim 18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-20 are generic and claims 1-3, and 12-20 are Markush-type claims.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 703 308-4231. The examiner can normally be reached on M_F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703 308-4025. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746-5137 for regular communications and 703 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

John S. Brusca
Primary Examiner
Art Unit 1631

jsb
July 16, 2002